

TO: Vermont Health Care Providers and Health Care Facilities
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Types of SARS-CoV-2 Tests

On August 6, 2020, the Council of State and Territorial Epidemiologists (CSTE) issued an [updated case definition](#) for coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As part of this updated case definition, laboratory evidence of this infection using a method approved or authorized by the U.S. Food and Drug Administration ([FDA](#)) was delineated as follows:

Confirmatory laboratory evidence:

- Detection of SARS-CoV-2 ribonucleic acid (RNA) in a clinical or autopsy specimen using a molecular amplification test (PCR)

Presumptive laboratory evidence:

- Detection of SARS-CoV-2 by antigen test in a respiratory specimen

Supportive laboratory evidence:

- Detection of specific antibody to SARS-CoV-2 in serum, plasma, or whole blood
- Detection of specific antigen by immunocytochemistry in an autopsy specimen

This update reviews characteristics of the currently available tests for SARS-CoV-2 infection.

Tests for detection of the virus (SARS-CoV-2): Currently there are two different types of tests for detection of SARS-CoV-2, each usually requiring a swab of the nose or nasopharynx:

- **A molecular test** (nucleic acid amplification test (NAAT) or polymerase chain reaction (PCR) test)
 - PCR assays are very sensitive (sensitivity approximately 95%), so there are few false negative results.
- **An antigen test** (to detect specific proteins on the surface of the virus)
 - Antigen tests are less sensitive than PCR assays, so there are more false negative results. Therefore, a negative test generally requires confirmation with a PCR assay.
 - Antigen tests are intended for people with symptoms of COVID-19. Antigen tests are particularly helpful when used to test people in the early stages of SARS-CoV-2 infection (within the first 5 to 7 days of symptoms compatible with COVID-19) when the SARS-CoV-2 viral load is generally the highest. Antigen tests should not be used to diagnose asymptomatic persons. They might be informative in diagnostic testing situations in which the person has a known exposure to a confirmed case of COVID-19.
 - Antigen tests may produce false positive results when disease prevalence is low.

- An advantage of antigen tests is that the results are usually available much more rapidly than results of PCR assays (i.e., within an hour versus same day or up to a week).

Note: The U.S. Department of Health and Human Services (DHHS) recently announced a large-scale procurement of FDA-authorized antigen test instruments and tests to be distributed to nursing homes and other settings across the U.S., including in Vermont. Antigen tests can be used for screening testing in high-risk congregate settings in which repeat testing could quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing transmission within the congregate setting. When used for screening in congregate settings, antigen test results should be considered presumptive. Confirmatory nucleic acid testing following a positive antigen test may not be necessary when the pretest probability is high, especially if the person is symptomatic or has a known exposure. When the pretest probability is low, those persons who receive a positive antigen test should isolate until they can be confirmed by RT-PCR. The Health Department will work with facilities that receive these instruments to report lab findings electronically.

Tests for detection of antibodies to SARS-CoV-2: Both immunoglobulin M (IgM) and immunoglobulin G (IgG) assays are available and are performed on a sample of blood. A positive result on a SARS-CoV-2 antibody assay can indicate recent or past infection. With other infections, IgM antibodies appear relatively quickly after infection while IgG antibodies appear later. There is limited information currently regarding: 1) the exact timing of appearance of IgM and IgG antibodies; and 2) the duration of detection of each of these types of antibodies after exposure to SARS-CoV-2. Currently, a positive antibody assay (especially an IgM antibody assay) result does not exclude a recent infection with the individual still being infectious. At this time, a positive SARS-CoV-2 antibody test cannot be used to determine whether an individual is immune to the virus. The results of antibody assays for SARS-CoV-2 may be available on the same day or within 1-3 days.

REQUESTED ACTIONS:

Utilize knowledge of the types of SARS-CoV-2 tests currently available when making decisions on which test to order for your patients.

[Report](#) all positive SARS-CoV-2 test results to the Health Department by calling 802-863-7240.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.